Principles for Writing SOPs

1 IDENTIFY NEED FOR NEW SOP

The steps that lead to the creation of a new SOP are broken down into the following broad procedures:

1.1 Requesting New SOPs

Request for a new SOP is put forward to the SOP Working Group under the CTMS Best Practice SIG. The user group member requesting the new SOP will complete the *New SOP Request Form* (TBD) and submit it for discussion by the SOP User Group.

1.2 Reviewing and Approving SOP Requests

Requests for new SOPs will be reviewed for completeness and to verify that the requested SOP does not exist or does require modification. The SOP request will be added to the agenda for the SOP Working Group Meeting. The SOP Working Group will vote on the approval and priority of all new proposed SOPs.

2 GATHER INPUT FOR SOP

After the SOP Working Group has approved the SOP request, collect and review relevant documentation (e.g. request, trigger, relevant working procedures etc) to start developing the body of the new SOPs. These documents should be listed as references in the SOP.

3 CREATE SOP

Describe the steps the SOP Working Group has taken to produce the first draft version of the relevant SOP, especially:

- **SOP Format**: The SOP Working Group has established a SOP template that will be used for all SOPs related to the clinical cancer research conducted under caBIG™
- **Process to Develop SOP**: Follow the procedure defined in the *SOP for Developing and Maintaining SOPs* to develop the draft SOP. Ensure all steps are addressed when describing the procedures that needs to be followed

3.1 Objective (Purpose)

Describe what the SOP is broadly required for (their rationale), as described in ICH E6 “Good Clinical Practice: A Consolidated Guideline” as well as in other regulatory or cancer site documentation requirements.

3.2 Scope

Describe the scope of this SOP (e.g., it is applicable to all SOPs prepared for clinical trials for which NCICB is the sponsor).

3.3 Requirements

Describe responsibilities of individuals and details of certain processes, inherent to the SOP.

3.4 References (Regulations and Guidelines)

List any references, which have been used for this SOP (e.g. ICH E6 Good Clinical Practice), updates of which may impact this SOP, also including regulations and NCI guidelines governing the application of this SOP.

3.5 Roles and Responsibilities

Describe the audience of this SOP. Ensure that all roles that have a core function in executing this SOP are included in this section. Describe what job responsibilities each role must complete as part of this standard procedure to accomplish the stated purpose or business function.

3.6 Attachments

List the documents that are included in the SOP by reference that are needed to fully understand how to execute the requirements listed in the SOP. This includes Procedure descriptions, and process flows.

4 REVIEW AND APPROVE SOP

The new SOP is submitted for review together with any supporting documentation to the SOP Working Group. The SOP Working Group will review and suggest necessary changes to the SOP before it is approved. The SOP will be reviewed in accordance with the *SOP for Developing and Maintaining SOPs*.

5 PROVIDE TRAINING ON SOP AND DISTRIBUTE SOP TO RELEVANT AUDIENCE

SOP Working Group will define the process and guidelines for providing training on new and updated SOPs. Approved SOPs will be distributed to adopters in electronic format on the caBIG web site.

6 REVISION AND DEVIATIONS OF SOPS

Revisions to SOPs will be done in accordance with the *SOP for Revising and Deviations SOPs* and NCICB documentation management guidelines and procedures. The process to ensure that the new SOP is released and the old version is removed from circulation is described as part of the *SOP for Release and Distribution*.

7 QUALITY ASSURANCE

In accordance with the *SOP for Developing and Maintaining SOPs*, new SOPs will undergo quality assurance (QA) review prior to approval. In addition, SOPs will be reviewed annually to ensure compliance with relevant regulatory guidelines and NCICB processes and standards.

8 GLOSSARY

Any new terms or abbreviations used in SOPs developed by NCICB should be incorporated into the *Glossary of Terms and Acronyms* or exist as part of the CDISC or caBIG™ vocabulary management system.